

REMARKS

Claims 1-33 are pending in the application. Claims 7 and 11 have been amended as suggested by the Examiner. No new matter has been added.

Claims 15-33 have been rejected under 35 USC§103(a) as allegedly unpatentable over Cleland et al. Applicants respectfully traverse this rejections.

The present invention is directed to an immunostimulating composition comprising encapsulating microspheres, wherein the encapsulating microspheres are:

- 1) a poly(DL-lactide-co-glycolide) bulk matrix with
- 2) an immunogenic substance made of a conformationally native subunit of chronic intracellular pathogen, which in the course of natural infection with that pathogen, is exposed to the host immune system on the surface of free pathogen and/or pathogen-infected cells.

In other words, the protein subunit is presented to the immune system of a host via a microcapsule formulation. The protein subunit elicits an immune response in the host.

Cleland, et al. is directed to microencapsulation of antigens and has been cited by the Examiner for its disclosure of encapsulating HIV. Cleland has a priority date of **October 22, 1993**. The present invention is a CIP of Ser. No. 242,960 and Ser. No. 446,149, filed May 22, 1995. Ser. No. 242,960 is a CIP of Ser. No. 867,301 filed **April 10, 1992**.

Ser. No. 867,301, from which this application claims priority, discloses encapsulating antigens to prevent infections caused by virus or bacteria. This application discloses encapsulating protein subunits to elicit an immune response. This application

discloses that microencapsulation of peptide subunits potentiates immune response to both the native protein and its linear peptide antigens.

These teachings pre-date the Cleland, et al. and show that the present inventors were the first to invent the concept of encapsulating an antigen in the form of a protein subunit.

Reconsideration and allowance are respectfully requested.

Respectfully submitted,



Date:

Oct. 23, 2002

For: Elizabeth Arwine, Reg. No. 45,867
Attorney for Applicant
U.S. Army Medical Research and Materiel
Command, Attn: MCMR-JA
521 Fraim Street
Fort Detrick, Maryland 21702-9223

Caroline M. Nash, Reg. No. 36, 329
Nash & Titus, LLC
3415 Brookeville Road
Suite 1000
Brookeville, Maryland 20833
Tel. No. (301) 924-9500
Fax. No. (301) 924-5883

Versions with markings:

IN THE CLAIMS:

Please amend the claims as follows:

7. (Twice Amended) A vaccine [comprising] consisting of a blend of immunostimulating compositions of claim 5.

11. (Twice Amended) A vaccine [comprising] consisting of a blend of immunostimulating compositions of claim 6.